IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W. R. GRACE & CO.-CONN., Plaintiff, v. ELYSIUM HEALTH, INC., Defendant.	C.A. No. 20-1098-GBW-JLH **REDACTED PUBLIC VERSION**

BRIEF IN SUPPORT OF PLAINTIFF'S
SUMMARY JUDGMENT AND DAUBERT MOTIONS

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I. Introduction

This patent infringement lawsuit relates to two novel crystalline forms of nicotinamide riboside chloride (NRCl), referred to as Forms I and II. The "Asserted Patents" are U.S. Patent Nos. 10,323,058 (Ex. 23, "the '058 patent"), 10,233,207 (Ex. 24, "the '207 patent"), and 10,189,872 (Ex. 25, "the '872 patent"). The '058 and '207 patents are directed to crystalline Form I NRCl and are referred to as the "Form I Patents." The '872 patent is directed to crystalline Form II NRCl and is referred to as the "Form II Patent."

[redacted]

Grace filed patent applications for Forms I and II in 2014 and 2015, respectively, and the United States Patent and Trademark Office (PTO) awarded Grace patents on both forms in 2019.

[redacted]

[redacted]

After Grace's Form I and Form II patents issued, Grace obtained samples of Elysium's "Basis" product, and tested them. Grace learned that Basis contained infringing forms of NRCl and filed the present lawsuit.

II. Summary Judgment Legal Standards

Summary judgement is appropriate if the movant shows that there is no genuine dispute as to any material fact. Fed. R. Civ. P. 56(a). Summary judgement should be granted against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. *SodexoMAGIC, LLC v. Drexel Univ.*, 24 F.4th 183, 204 (3d Cir. 2022). Where the non-moving party has the burden of proof, the movant can prevail by demonstrating an absence of evidence to support the non-moving party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-5 (1986).

III. Motion No. 1: Summary Judgement of No Inequitable Conduct

Elysium alleges that inventor Erik Carlson and other named and unnamed individuals at Grace (including "at a minimum" Brett Reynolds, a Grace business director) committed inequitable conduct because they intentionally failed to disclose to the United States Patent and

Trademark Office ("PTO") "information" concerning Grace's purported pre-critical date offers and sales of "crystalline" nicotinamide riboside chloride ("NRCl").[1] (SMF ¶¶4, 12.) Elysium alleges these alleged pre-critical date transactions would have been an on-sale bar under 35 U.S.C. § 102 because the material allegedly offered or sold purportedly contained Grace's patented crystalline Form I and/or Form II NRCl. (SMF ¶¶5-6.) Elysium failed to adequately plead its inequitable conduct allegations and therefore its inequitable conduct defenses and counterclaims should be dismissed on the pleadings for all of the reasons set forth in Grace's motion to dismiss these claims pursuant to Rule 12(b)(6). (*See* D.I. 136.) But even if the Court declines to dismiss pursuant to Rule 12(b)(6), it should grant summary judgment for Grace on Elysium's inequitable conduct claims because Elysium cannot prove that any individual owing a duty of candor to the PTO ***intentionally*** withheld information that he or she ***knew*** to be material from the PTO.

It is undisputed that NRCl can exist in multiple forms. (SMF ¶16.) For example, NRCl can exist in amorphous (*i.e.*, non-crystalline) forms or in various crystalline forms. *Id.* The Asserted Patents are directed to two specific crystalline forms, Form I and Form II. The Court's claim construction requires that the claimed forms be identified by "one or more of the analytical methods described in the specification" using testing data. (SMF ¶¶18-20.) Put differently, the claim construction confirms the scientific fact that ***it is not possible to identify the claimed forms visually—i.e., by merely looking at the material or by reading about its physical description—without analytical testing and data***. (*Id.*) It is also undisputed that other crystalline forms of NRCl distinct from Grace's Form I and Form II exist. (*See id.* ¶17.)

[1] The relevant facts are laid out in Grace's accompanying Concise Statement of Material Facts ("SMF") in support of its Summary Judgement Motion of No Inequitable Conduct.

Elysium must prove by clear and convincing evidence that a specific individual at Grace acted with specific intent to deceive the PTO by withholding the alleged information. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). To meet its burden, Elysium must produce clear and convincing evidence that someone at Grace: (1) knew of the pre-critical date offers and sales, (2) knew of their purported materiality—***which could only be known through analytical testing and data***, and (3) made a deliberate decision to withhold that information. *Id.* But Elysium has adduced no evidence that anyone at Grace knew or believed that either patented form was commercially offered or sold before its applicable critical date. [redacted] Elysium cannot show specific intent to deceive, and summary judgement of no inequitable conduct is warranted.

A. <u>Inequitable Conduct Legal Standard</u>

Among other things, Elysium must show by clear and convincing evidence that an individual having a duty of disclosure acted with the specific intent to deceive the PTO by withholding material information from the examiner. *Therasense*, 649 F.3d at 1290. The proof of intent must be "clear and convincing evidence that the applicant knew [the relevant information], knew that it was material, and made a deliberate decision to withhold it" as part of a scheme to

deceive the PTO. *Id.* A failure of proof on any element precludes finding inequitable conduct as a matter of law.[2] *See 1st Media, LLC v. Electronic Arts, Inc.*, 694 F.3d 1367, 1372 (Fed. Cir. 2012).

Because there is no direct evidence of an intent to deceive, Elysium must prove by clear and convincing evidence that specific intent to deceive is the single most reasonable inference to be drawn from the circumstantial evidence. *Therasense*, 649 F.3d at 1290. Specific intent to deceive cannot be found if there are multiple reasonable inferences to be drawn from the evidence. *Id.* at 1290-91. Proving that patentee knew of information, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive. *Id.* Where the non-moving party cannot show specific intent, summary judgement is proper. *See AstraZeneca Pharms. LP v. Teva Pharms. USA Inc.*, 583 F.3d 766, 776-77 (Fed. Cir. 2009); *Trading Techs. Int'l, Inc. v. IBG LLC*, 2020 WL 7013964, at *5 (N.D. Ill. Nov. 29, 2020).

B. Elysium Failed to Name the Specific Individuals Who Allegedly Committed Inequitable Conduct

Elysium must prove by clear and convincing evidence that an ***individual*** having a duty of disclosure—not a corporation or an institution—acted with the specific intent to deceive the PTO. Therefore, Elysium must identify the specific ***individual or individuals*** who it alleges acted with specific intent to deceive and their ***associated acts*** which constitute the requisite intent. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009) (pleading inequitable conduct must include sufficient allegations of underlying facts from which it may be inferred that a specific individual knew of information and withheld it with specific intent).

[2] A separate, independent element of proof required to establish inequitable conduct under *Therasense* is "but-for materiality," which requires showing that the PTO would not have allowed a claim if it had been aware of the information that was not disclosed. *See id.* at 1291-92. It is unnecessary for Grace to demonstrate Elysium's failure to establish this second, independent element of inequitable conduct to prevail on its summary judgement of no inequitable conduct.

Elysium's generic allegations of what an entire organization like Grace collectively knew or did (*see* SMF ¶¶4, 11, 37-39.) are insufficient to establish specific intent.[3] *Id.* at 1330-31. [redacted]

Even if assumed true, these generic assertions fail as matter of law.

C. There is No Evidence Anyone Knew the Information Was Material or Made a Deliberate Decision to Withhold It

The only individuals Elysium specifically named in its counterclaims are inventor Erik Carlson and Brett Reynolds, a Grace Global Business Director who is not an inventor. (SMF ¶12.) But even assuming Mr. Carlson and Mr. Reynolds knew about any alleged pre-critical date transactions, there is no evidence that either one knew of the purported ***materiality*** of those transactions.

As explained above, Forms I and II are identified by analytical testing data. [redacted]

Thus, for Elysium's theory of inequitable conduct to survive, it must be premised on allegations that Mr. Carlson and Mr. Reynolds allegedly knew about analytical testing and data (SMF ¶¶18-20) purportedly establishing that "Form I" and "Form II" were sold before the critical dates (SMF ¶¶4-6.) But Elysium adduces no evidence that anyone at Grace knew or was aware of analytical testing data establishing that Forms I or II were sold before their respective critical dates.

[3] Dismissal of Elysium's generic allegations is warranted for the reasons explained in Grace's pending Motion to Dismiss Defendant's Inequitable Conduct Counterclaims and Strike Related Affirmative Defense. (*See* Dkt. No. 136.)

[redacted] Elysium points to no evidence that Mr. Reynolds or Mr. Carlson knew or believed that Grace sold crystalline Form I or Form II NRCl before their respective critical dates.

[redacted]

[redacted] Despite extensive discovery, Elysium cannot point to direct evidence indicating that anyone at Grace knew of the purported materiality of the pre-critical date transactions or that anyone made a deliberate decision to withhold such information.

D. The Circumstantial Evidence Fails to Establish That Anyone Had Specific Intent to Defraud the PTO

Because there is no direct evidence of intent, Elysium attempts to rely on circumstantial evidence and speculation as to what Mr. Carlson and other unnamed individuals at Grace—including so-called "competent patent professionals"—allegedly knew and did during prosecution of the Asserted Patents. Elysium attempts to make this proffer through its ostensible "in-house patent law expert," Robert Armitage. (SMF ¶¶36-41.)

[redacted]

Fundamentally, Elysium has Mr. Armitage supply the "evidence" of specific intent that fact discovery did not reveal.

[4] Dismissal of Elysium's allegations against unnamed Grace employees is warranted for reasons explained in Grace's pending motion to dismiss. (*See* D.I. 136.)

No patent professionals have been accused of committing inequitable conduct. In fact, Elysium told the Court it would not depose Grace's patent prosecutors or seek discovery of their documents because "***frankly, that's not our theory of the claim. Our theory of the claim is that the inventors lied***." (SMF ¶13 (emphasis added).) Thus, the conduct of patent professionals is not germane to any issue here.[5] But even if Mr. Armitage's allegations are assumed to be true, there is still no evidence that any ***named individual*** at Grace acted with specific intent to deceive the PTO. Mr. Armitage's generic allegations regarding Grace, as a whole, fail to provide the requisite evidence of specific intent.

Elysium must prove that a named individual at Grace knew of the information, knew that it was material to patentability, and made a deliberate decision to withhold it. *See Therasense*, 649 F.3d at 1290. But here, Elysium cannot meet even a threshold requirement of showing that anyone knew the alleged information was material to patentability. While the court may infer intent from circumstantial evidence, specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence. *Id*. "When there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Id.* at 1290-91. [redacted]

The record evidence does not indicate that Mr. Carlson and Mr. Reynolds hid anything that identified the claimed Forms prior to the critical dates. [redacted]

[5] *See* Grace's Daubert Motion to Exclude Testimony of Robert Armitage in its Entirety (*infra* VIII).

[redacted] Thus, Elysium's alleged inference of deceptive intent cannot be considered reasonable, and intent to deceive cannot be found.

[redacted] For example, Mr. Carlson testified he did not think IR data by itself is sufficient to characterize a crystal form. (SMF ¶32.) In fact, Elysium's experts admitted Grace employees did not believe IR data was indicative of a crystal form. (SMF ¶27.) [redacted] Thus, Elysium's alleged inference of deceptive intent cannot be considered reasonable, and intent to deceive cannot be found.

In addition, Mr. Armitage admitted that he did not attempt to determine the "competence" of any patent professional representing Grace and that nothing in his report was designed to address issues of negligence of any patent professionals employed by Grace. (SMF ¶¶40-41.) Assuming *arguendo* that Mr. Armitage's narrative was deemed reasonable, there would be at least one other reasonable inference here. [redacted]

[redacted] *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1353 (Fed. Cir. 2008) ("Mistake or negligence, even gross negligence, does not support a ruling of inequitable conduct."). Because there are multiple reasonable inferences that can be drawn based on the circumstantial evidence, Elysium cannot show specific intent to deceive the PTO. *See, e.g., Therasense*, 649 F.3d at 1290-91. Accordingly, no genuine issue regarding inequitable conduct exists for trial and summary judgment is warranted. *See Trading Techs.*, 2020 WL 7013964, at *5; *Fujitsu Ltd. v. Tellabs Operations, Inc.*, 2012 WL 3133548, at *4 (N.D. Ill. July 31, 2012); *Remediation Prods., Inc. v. Adventus Americas, Inc.*, 2011 WL 13217088, at *10 (W.D.N.C. Dec. 19, 2011).

IV. Motion No. 2: Partial Summary Judgment of No Invalidity Under § 102

Elysium contends that the Form I Patents are invalid as anticipated under 35 U.S.C. § 102 for having been "on sale" more than one year before the patents' earliest priority date of July 24, 2014. In support, Elysium points to at least eight of the batches of nicotinamide riboside chloride (NRCl) that Grace manufactured in 2013 and 2014, which have batch numbers 13101-23 through 14209-22. [redacted] Consequently, those batches cannot have been "on sale" before the critical date. Elysium appears to argue that the purchase orders must have been

based upon some prior negotiations or discussions, and therefore contends that the "offer for sale" of each batch must have occurred on some earlier, unspecified date before the purchase orders were issued. But Elysium does not present any evidence showing that a contractual offer for sale took place before the critical date for any of these batches.

[redacted] Thus, the Court should grant summary judgment that any alleged offer or sale of NRCl batches 13201-92 through 14209-22 does not anticipate the Form I Patents.

A. Background

[redacted]

[6] The relevant facts are laid out in Grace's accompanying Concise Statement of Material Facts ("SMF") in support of its Motion For Partial Summary Judgement of No Invalidity Under § 102.

[redacted]

B. On-Sale Bar Legal Standards

Elysium contends that the asserted claims of the Form I Patents are invalid under 35 U.S.C. § 102 for being "on-sale." To prevail, Elysium must prove by clear and convincing evidence that prior to the "critical date" (i.e., more than one year before the Form I Patents' earliest priority date), the claimed invention was (1) the subject of a commercial offer for sale, and (2) ready for patenting. *Sysmex Corp. v. Beckman Coulter, Inc.*, 2022 WL 2111221, at *2 (D. Del. June 9, 2022) (citing *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998)). A failure to prove either prong warrants summary judgment. *Id*. at *1-3; *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1048-49 (Fed. Cir. 2001) (holding that because no commercial offer for sale was made, the Court "need not address . . . the second prong of *Pfaff*"). To meet the first prong, "the offer must meet the level of

[7] Elysium appears to contend, without evidence, the witnesses are lying about when Grace personnel first knew of Form I. But resolution of this issue is not necessary for this motion.

an offer for sale in the contract sense, one that would be understood as such in the commercial community." *Grp. One*, 254 F.3d at 1046 (citations omitted). "[A]ctivity which does not rise to the level of a formal 'offer' under contract law principles" is not a commercial offer for sale. *Id.* at 1046-47.

C. Elysium Cannot Prove That Grace Batches 13202-95 Through 14209-22 Were Offered for Sale or Sold Before the Form I Patents' Critical Date

Elysium relies upon the purchase order dates for NRCl batches 13202-96 through 14209-22 to support its contention that these batches constitute an on-sale bar to the Form I Patents. [redacted] But even assuming that the foregoing purchase orders were commercial offers for sale of Form I,[8] those offers would not have taken place before the critical date. [redacted] Thus, Elysium cannot prove that these batches were sold or offered for sale before the critical date.

[8] [redacted] This means that the existence of a purchase order alone does not evidence the consummation of a commercial sale or offer for sale. Rather, a sale was only completed if Grace later ***accepted*** the purchase order.

Elysium appears to argue that the purchase orders must have been based upon prior negotiations of terms, and therefore the "offer for sale" of each batch must have occurred on some earlier, unspecified date before the purchase order was issued. (*See, e.g.,* Ex. 3, Perni Opening Report ¶¶ 85, 109; Ex. 4, Steed Opening Report ¶ 95). [redacted] But Elysium points to no evidence of particular discussions or negotiations for the batches in question, no less any discussions for a particular form of NRCl. And Elysium cannot prove that any such earlier discussion or negotiations that may have taken place rose to the level of a contractual offer to sell NRCl.

In addition, even if one were to assume, without evidence, that a formal contractual offer must have been made before the purchase orders were issued, Elysium can point to no evidence that such contractual offers for batches 13202-96 through 14209-22 were made ***before*** the critical date. [redacted] There is simply no evidence of whether and when such negotiations occurred, or when they rose to the level of a formal contractual offer. [redacted] Thus, Elysium cannot prove by clear and convincing evidence that formal contractual offers for sale with respect to batches 13202-96 through 14209-22 were made before the Form I Patents' critical dates. The Court should grant summary judgment that the Form I Patents are not invalid under the on-sale bar based on those batches.

D. <u>Elysium Cannot Prove That Grace Batches 13201-92 and 13201-95 Were Offered for Sale or Sold Before the Form I Patents' Critical Date</u>

[redacted]

"[A]ctivity which does not rise to the level of a formal 'offer' under contract law principles" is not a commercial offer for sale. *Grp. One*, 254 F.3d at 1046-47. In *Linear Technology Corp. v. Micrel, Inc.*,275 F.3d 1040, 1052-54 (Fed. Cir. 2001), the Federal Circuit reversed a finding of invalidity under the on-sale bar because, although Linear Technology Corp ("LTC") received purchase orders for its LT1070 silicon chips and entered these into its system, this was insufficient to form a valid contract and thus failed prong one of *Pfaff*. Prior to the critical date, LTC received purchase orders from foreign distributors for the later patented LT1070 chips. *Id*. at 1052. These purchase orders, which the Court characterized as "offers to buy," were later filled after the critical date. *Id*. Prior to the critical date, LTC had entered these purchase orders into its booking system and issued "will-advise confirmations" to the foreign distributors. *Id*. "An offer is the manifestation of willingness to enter into a bargain, so made as to justify another person in understanding that his assent to that bargain is invited and will conclude it." *Id.* at 1050 (citing Restatement (Second) of Contracts § 24 (1981)). The Court held that "[i]n order to be effective, an acceptance must *objectively* manifest the offeree's assent" and that "even if LTC privately intended to accept the offers, it did not form a contract until it objectively communicated this fact to the distributors," which the "will-advise confirmations" did not. *Id*. at 1053. The Court further

held that the record was "devoid of any evidence, testimonial or otherwise, as to what the distributors actually understood when they received the will-advise confirmations." *Id*. at 1054.

Here, Elysium similarly contends that batches 13201-92 and 13201-95 were offered for sale based on purchase orders issued before the critical date but fulfilled after it. (*See* Ex. 16, Elysium's Amended Invalidity Contentions at p. 40.) Yet the evidence shows that [redacted], like those in *Linear Tech.*, [redacted] As in *Linear Tech.*, Elysium cannot prove that [redacted] Thus, Elysium cannot prove by clear and convincing evidence that formal contractual offers for sale with respect to batches 13201-92 and 13201-95 were made before the Form I Patents' critical dates. The Court should grant summary judgment that the Form I Patents are not invalid under the on-sale bar based on those batches.

V. Motion No 3: Summary Judgement of No Alleged Non-Infringing Alternatives Available to Elysium

Summary judgment that Elysium's alleged non-infringing alternatives were not available to Elysium during the infringement period is warranted. Elysium alleges it could have redesigned

its Basis product to avoid Grace's patents in one of three ways by replacing its accused infringing NRCl ingredient with: [redacted] But there is no dispute that these alleged non-infringing alternatives were never sold or marketed during the infringement period, which began in January 2019.[9] (SMF ¶¶2, 5, 17, 25.) Elysium therefore has the burden to overcome the inference of unavailability and prove its alleged substitutes were available. *Grain Processing*, 185 F.3d at 1353. Critically, the "trial court must proceed with caution in assessing proof of the availability of substitutes not actually sold during the period of infringement." *Id.* And because Elysium ignored its various alleged substitutes in favor of Grace's patents, any attorney argument that Elysium's alleged substitutes would have been acceptable is suspect. *See TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 902 (Fed. Cir. 1986). But here, because Elysium has raised only conclusory assertions of availability, it cannot raise any genuine fact issues. *See Id*.

"When an alleged alternative is not on the market during the accounting period, a trial court may reasonably infer that it was not available as a noninfringing substitute at that time." *DePuy Spine. Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1331 (Fed. Cir. 2009) (quoting *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1353 (Fed. Cir. 1999)). For Elysium's alleged "alternatives" to NRCl in its accused product that were never marketed, it has the burden to prove they were "available." *Grain Processing*, 185 F.3d at 1353-54. Substitutes "only theoretically possible" will not preclude lost profits. *Id.*; *see Micro Chem. Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1123 (Fed. Cir. 2003).

[9] The relevant facts are laid out in Grace's Concise Statement of Material Facts ("SMF") accompanying its Motion for Summary Judgement of No Alleged Non-Infringing Alternatives Available to Elysium.

[redacted] But there is no evidence that Elysium "had all of the necessary equipment, know-how, and experience" to implement its alleged [redacted] design around during the infringement period. *Grain Processing*, 185 F.3d at 1354.

[redacted] Rather, Mr. Clemons testified he ***assumed*** that a hypothetical [redacted] "could be performed by various suppliers who are – you know, have skilled technicians that synthesize these types of products." *Id.* [redacted] Elysium's assertion that [redacted] could have been an available substitute during the infringement period is far too speculative, as a matter of law, to defeat Grace's claim for lost profits. *See Micro Chem.*, 318 F.3d at 1123 (alternative not available where it took 4 months to convert to non-infringing devices).

[redacted] But there is no evidence that Elysium could have commercialized Basis with [redacted] Mr. Clemons could not identify any commercially available sources of [redacted] during the damages period. (SMF ¶¶19-20.) Mr. Clemons also did not know what it would cost Elysium to purchase [redacted] and provided no analysis or quantification of what costs Elysium would incur to switch [redacted] Elysium's assertions regarding [redacted] are far too speculative as a matter of law to defeat a claim for lost profits. *See, Micro Chem.*, 318 F.3d at 1123.

[redacted] Mr. Clemons presented no quantification or analysis of what it would take for Elysium to make such as switch. (SMF ¶31.) Nor is there any evidence that a version of Basis containing [redacted] would be an acceptable substitute to Elysium's customers. [redacted] Elysium's assertions regarding [redacted] are far too speculative as a matter of law to defeat a claim for lost profits. *See*

Micro Chem., 318 F.3d at 1123; *TWM*, 789 F.2d at 901 (product lacking patented advantages can hardly be termed an acceptable substitute).

Elysium's allegations with respect to its remaining non-infringing alternatives are even more conclusory. For example, Mr. Clemons testified that once he had analyzed Elysium's "more obvious non-infringing alternatives" [redacted] his analysis of the "additional non-infringing alternatives are really more to illustrate the fact there are many, many non-infringing alternatives ***potentially available***, and it wasn't relevant to . . . ***dig into each of them to the same level of rigor*** as I did the more likely non-infringing alternatives that Elysium might implement in the but-for world." (SMF ¶34 (emphasis added).) Accordingly, summary judgment that Elysium's alleged non-infringing alternatives were not available to Elysium during the infringement period is warranted.

VI. Motion No. 4: Partial Summary Judgement of No Invalidity Under 35 U.S.C. § 112

Elysium contends that the patents-in-suit are invalid for failure to meet the enablement and written description requirements of 35 U.S.C. § 112. But Elysium has no expert testimony or any other evidence to support its contentions. In fact, its experts do not even attempt to analyze the applicable requirements for enablement and written description. Elysium appears to rely solely on inventor testimony, which is improper. Because Elysium has no evidence that the asserted claims are invalid, summary judgment is appropriate.

A. Elysium Cannot Prove That the Asserted Claims of the Patents-in-Suit Are Invalid for Lack of Enablement

Elysium presents no evidence demonstrating that the patents-in-suit are not enabled. "[E]nablement requires that the specification teach those in the art to make and use the invention without ***undue experimentation***." *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988) (emphasis

added). Whether experimentation is "undue" is a "conclusion reached by weighing many factual considerations." *Id.* The relevant "*Wands*" factors include but are not limited to:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims

Id. Where, as here, the patented subject matter is "sufficiently complex to fall beyond the grasp of an ordinary layperson," the patent challenger must "present expert testimony in order to establish invalidity." *Proveris Sci. Corp.*, 536 F.3d at 1267. An expert's "cursory consideration" of the *Wands* factors or "unsubstantiated statements indicating that," for example, "experimentation would be 'difficult' and 'complicated' are not sufficient." *Cephalon, Inc. v. Watson Pharms., Inc*., 707 F.3d 1330, 1340, n.11 (Fed. Cir. 2013).

Here, Elysium's technical experts, Drs. Perni and Steed, do not allege that a POSA would not have been able to make Form I or Form II NRCl using the processes described in the patents-in-suit. Instead, they contend that the patents are not enabled because they do not "enable a POSA ***to identify the claimed invention***." (Ex. 4, Steed Opening Rpt. at ¶185; Ex. 3, Perni Opening Rpt. at ¶200 (emphasis added).) But other than a single conclusory and unsupported reference to "undue experimentation," they do not analyze the nature and quantity of experimentation that would be needed to identify the claimed crystalline forms using the disclosed analytical methods. Moreover, Drs. Steed and Perni ***did not discuss <u>any</u> of the Wands factors***.

In actual fact, it is undisputed that the Form I Patents provide data from six different analytical methods for Form I NRCl and the '872 patent provides data from four different

analytical methods for Form II NRCl.[10] (SMF ¶¶1-2.) And it is undisputed that a POSA would have had experience and education concerning all of the analytical methods described in the patents-in-suit. (*Id.* ¶3.) Drs. Steed and Perni fail to consider whether the patent specifications, together with the knowledge a POSA would indisputably possess based upon her experience and education, would enable her to identify the claimed crystalline forms using one or some combination of those methods. Additionally, Dr. Steed purportedly identified the crystalline form of NRCl contained in retained samples of various Grace NRCl batches made in 2013 using only x-ray powder diffraction data provided by a third-party laboratory and the x-ray powder diffraction data disclosed in the patents-in-suit. (*Id.* ¶4.) The patents seemingly gave Dr. Steed enough information to purportedly identify the crystalline form(s) contained in the samples, contradicting his and Dr. Perni's opinions that the patents lack such information. (*See id.*)

Lacking any other evidence, Elysium and its experts rely on inventor deposition testimony regarding the analytical methods described in the patents-in-suit. (Ex. 3, Perni Opening at ¶¶195-196, 198-200; Ex. 4, Steed Opening at ¶¶181, 183-185.) This is improper and insufficient. Enablement must be determined from the perspective of a POSA reading the patent application. Inventor deposition testimony cannot be used to invalidate the claims under Section 112 after they have been issued. *See, e.g., Solomon v. Kimberly-Clark Corp.,* 216 F.3d 1372, 1377 (Fed. Cir. 2000); *Hitkansut LLC v. United States*, 119 Fed. Cl. 258, 263 n.6 (2014).

B. Elysium Cannot Prove That the Claims of the Asserted Claims of the Patents-in-Suit Are Invalid for Lack of Written Description

Elysium further contends that the specifications of the patents-in-suit are invalid for lack of written description support because, *inter alia*, "[t]he respective claims in light of the patent

[10] The relevant facts are laid out in Grace's accompanying Concise Statement of Material Facts ("SMF") in support of its Motion For Partial Summary Judgement of No Invalidity Under § 112.

specifications and Court's claim construction . . . provide no guidance to a person of ordinary skill in the art with an understanding of the metes and bounds of claim 1 of the '207 patent, claim 1 of the '058 patent, claim 1 of the '872 patent, and all their respective dependent claims." (Ex. 4, Steed Opening at ¶173; Ex. 3, Perni Opening Rpt. at ¶186.) Elysium further contends that "those claims cover a broad genus that is not adequately described because its scope is unknown and a POSA would not understand how to evaluate the scope of the claimed invention." (Ex. 4, Steed Opening Rpt. at ¶178; Ex. 3, Perni Opening Rpt. at ¶191.)

The proper inquiry for the written description requirement is whether the patent specification sufficiently describes the claimed invention such that that a POSA reading the disclosure could reasonably conclude that the inventor had possession of the invention. *Ariad Pharms., Inc. v. Eli Lilly & Co.*,598 F.3d 1336, 1344-45 (Fed. Cir. 2010) (*en banc*). Here, it is undisputed that the patents-in-suit provide analytical data from multiple different techniques for each of the claimed crystalline forms and also provide scanning electron microscope images of the crystals. (SMF ¶¶1-2, 5) Elysium presents no evidence whatsoever showing that a POSA would not recognize that the inventors were in possession of the claimed invention. Its scientific experts, Drs. Steed and Perni do not discuss possession of the invention at all in their expert reports. *See Proveris Sci. Corp..*, 536 F.3d at 1267 (expert testimony required where invention is "sufficiently complex to fall beyond the grasp of an ordinary layperson").

Because Elysium presents no evidence and cannot prove by clear and convincing evidence that the asserted claims are invalid for lack of enablement or written description, the Court should grant summary judgment in favor of Grace that the patents-in-suit are ***not invalid*** for lack of enablement and written description.

VII. FRE 702, 403, and *Daubert* Standards

Rule 702 allows for opinion testimony from a qualified expert if the following requirements are each met: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case. Fed. R. Evid. 702. The party offering the testimony has the burden to prove admissibility. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 n. 10 (1993).

Under Federal Rule of Evidence 403, a "court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Courts have "broad discretion" to exclude relevant evidence under Rule 403. *United States v. Heinrich*, 971 F.3d 160, 163 (3d Cir. 2020).

VIII. Motion to Exclude Testimony of Robert Armitage in its Entirety

The Court should exclude the testimony of Elysium's purported in-house patent law expert, Robert Armitage, in its entirety as irrelevant, unreliable, and unfairly prejudicial. Because Elysium has not accused any patent attorneys of committing inequitable conduct, Mr. Armitage's opinions about what a "competent patent professional" employed by Grace would allegedly have known and understood during prosecution are not germane to any issues here. The Armitage reports amount to nothing more than improper legal opinions about what certain facts allegedly indicate about materiality, intent, and what the examiner might have done had circumstances been different. In line with the consistent practice of this District, Mr. Armitage should not be permitted to offer such testimony here. *See, e.g.*, *Purewick v. Sage Products, LLC*, 2021 WL 2593338, at *1 (D. Del. Jun. 24, 2021).

A. Legal Expert Testimony is Typically Excluded

Delaware courts "have a well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances." *AstraZeneca UK Ltd. v. Watson Labs., Inc.*, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012); *Lannett Co, Inc. v. KV Pharm.*, 2009 WL 10657988, at *5 (D. Del. Mar. 9, 2009). "[I]t is the Court's function to determine the applicable legal standards." *Id.* *4. Accordingly, testimony of patent law experts is narrowly constrained. *See AstraZeneca*, 2012 WL 6043266, at *2 (expert cannot opine regarding intent); *Ondeo Nalco Co. v. EKA Chems., Inc.*, 2003 WL 1524658, at *3 (D. Del. Mar. 21, 2003) (expert cannot opine regarding what PTO would have done if information had been submitted).

B. Mr. Armitage's Opinions are Irrelevant to any Claim or Defense

Mr. Armitage does not identify any claim or defense to which his reports relate. He states he was asked to opine on "how a competent patent professional would address issues such as the duty of disclosure and duty of inquiry" during prosecution. (Ex. 26, Armitage Opening, at ¶10.) And he concludes that a competent patent professional would have understood Grace's alleged pre-critical date activities were material to patentability. (Ex. 8, Armitage Reply, at ¶¶15 n.12, 26.) The only issue that Mr. Armitage's reports could potentially be relevant to is inequitable conduct. But Elysium has not accused any patent professionals of committing inequitable conduct here. Rather, Elysium clearly represented to the Court that it was targeting the "inventors" because they purportedly "lied," and that it did not intend to pursue depositions of prosecuting attorneys or seek patent prosecution files. (Ex. 10, Armitage Tr., at 74:18-21; 78:12-17). The conduct of patent professionals is not germane to any issues here, and Mr. Armitage's proposed testimony should be excluded.

C. Testimony Concerning "Competent Patent Professionals" is Improper

Mr. Armitage attempts to supply the missing evidence of specific intent by offering testimony about an irrelevant standard of care (*i.e.*, "competence") and then speculating that certain individuals at Grace ***must have known*** certain facts—not that they actually did—because a competent patent professional allegedly would have [redacted] He then states that if a "competent patent professional" would have gained access to this "information," they allegedly would have understood this information to be material to patentability. (*Id.* at ¶29.) [redacted]

Mr. Armitage's attempted end run around Elysium's burden of proof on specific intent is impermissible. Critically, his proposed testimony about competent patent professionals is irrelevant to whether Elysium can prove that any individual at Grace had the requisite specific intent to deceive the PTO. Because Mr. Armitage relies on the construct of a "competent patent professional," at most his opinions may bear on issues of mistake or negligence. But if all Elysium can establish is the possibility that the attorneys who prosecuted the patents may have acted negligently or without competence, that would negate intent to deceive as the single most reasonable inference to be drawn from the circumstantial evidence. *See Abbott*, 544 F.3d at 1353.

Even if the standard of care for patent professionals was otherwise relevant, Mr. Armitage is not qualified to proffer any opinions on the conduct of a competent patent

professional. He was unable to define what level of training or experience would qualify someone as a "competent patent professional." (Ex. 10, Armitage Tr., at 27:20-28:23.) And he admitted he did not attempt to determine whether Grace's patent attorneys may have lacked competence or acted negligently. (*Id.* at 39:5-25, 130:25-131:6.) And in any event, Mr. Armitage's standard of care opinions are filled with improper speculation about what certain facts allegedly indicate about materiality and intent. *Victaulic Co. v. ASC Engineered Sols., LLC*, 2022 WL 17250376, at *8 (D. Del. Nov. 28, 2022) (testimony that merely substitutes the expert's judgement for the jury's would not be helpful). Mr. Armitage's proposed testimony would put an "expert's imprimatur" on his personal belief as to the weight of the evidence and should be excluded. *Id.*

D. Mr. Armitage Improperly Opines on the Law, Including the Wrong Materiality Standard

Mr. Armitage's Improper opinions on the law should be excluded. For example, Mr. Armitage repeatedly applies the incorrect legal standard for assessing materiality by relying on 37 C.F.R. § 1.56 ("Rule 56") throughout his reports. (*See, e.g.*, Ex. 26, Armitage Opening, at ¶100 (opining that if information had been submitted, patent examiner "would have [had] more than enough information" to find that "*prima facie* unpatentability had been established—at least under the applicable preponderance of the evidence standard").) The legal standard governing a violation of the Rule 56 differs from inequitable conduct in two critical ways.

First, the materiality analyses are different. Inequitable conduct generally requires "but-for" materiality, meaning undisclosed prior art is "material" only if the PTO would not have allowed a claim had the art been disclosed. *Therasense*, 649 F.3d at 1291. By contrast, Rule 56 sets a substantially lower bar for materiality, under which information is "material" if it is noncumulative and either (1) establishes, by itself or in combination with other information, a

prima facie case of unpatentability of a claim; or (2) it refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the PTO, or (ii) asserting an argument of patentability. 37 C.F.R. § 1.56. The Federal Circuit expressly declined to adopt to Rule 56 standard for inequitable conduct expressly because it "sets such a low bar for materiality." 649 F.3d at 1295. ***Second***, inequitable conduct requires specific intent to deceive. *Id.* at 1290. By contrast, Rule 56 apparently imposes no intent requirement at all. This must be the case because Mr. Armitage states he does not intend to offer "any opinions as to the intent or actual state of mind" of anyone (Ex. 8, Armitage Reply, at ¶7), yet he is able to conclude that under certain premises a competent patent professional would have violated Rule 56. (*Id.* at ¶9.)

Hebert v. Lisle Corp., 99 F.3d 1109 (Fed. Cir. 1996), is instructive. There, the Federal Circuit reversed a judgment of unenforceability because the evidence at trial—which included testimony from patent law experts relating to inequitable conduct and duties of disclosure—was insufficient to support the jury's verdict. *Id.* at 1115-17. The Court "[took] note of the extent to which the ***incorrect law*** was announced by a patent law expert witness." *Id.* at 1117 (emphasis added). The Federal Circuit admonished trial courts to exercise their gatekeeper authority when parties proffer, "not only unproven science, but markedly incorrect law." *Id.*

As described above, Mr. Armitage applies the wrong materiality standard in his reports. His reports also include various other self-serving opinions about what the law is and what it means. (*See, e.g.*, Ex. 26, Armitage Opening, at ¶¶38, 52-53.) In line with *Hebert* and the consistent practice of this District, Mr. Armitage should not be permitted to offer testimony on incorrect law. *See, e.g., Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.*, 2022 WL 806524, at *3 (D. Del. Feb. 08, 2022); *Baxalta Inc. v. Bayer Healthcare LLC*, 513 F. Supp. 3d

426, 448 (D. Del. 2021); *Intuitive Surgical, Inc. v. Auris Health, Inc.*, 549 F. Supp. 3d 362, 370 (D. Del. 2021); *Sprint Commc'ns Co. L.P. v. Cox Commc'ns Inc.*, 302 F. Supp. 3d 597, 624 (D. Del. 2017). Nor should Mr. Armitage be permitted to testify on what the law is or offer conclusions concerning a party's compliance with legal duties. *See Purewick*, 2021 WL 2593338, at *1; *Brigham and Women's Hospital, Inc. v. Teva Pharms. USA, Inc.*, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010).

E. Mr. Armitage's Construction of a Factual Narrative Is Not Helpful

[redacted] And his opinions are not technical in nature. [redacted] Mr. Armitage should not be presented to the jury solely for the purpose of putting his expert's imprimatur on constructing a factual narrative based upon record evidence. His opinions should be excluded. *Victaulic*, 2022 WL 17250376, at *7-8 (excluding expert testimony that was not technical and prejudicial); *PureWick*, 2021 WL 2593338, at *1; *f'real Foods, LLC v. Hamilton Beach Brands, Inc.*, 2019 WL 1578259, at *1 (D. Del. Apr. 11, 2019).

F. Speculation About Other People's State of Mind Including the Examiner's Should Be Excluded

As described above, the Armitage reports are filled with unfounded speculation concerning what unnamed individuals at Grace would have allegedly known and understood

about the facts. (*See* Ex. 26, Armitage Opening at ¶79 (speculating as to beliefs at Grace regarding on-sale bar issues); [redacted] Mr. Armitage has no basis for this speculation and his testimony is improper. *See In re Rosuvastatin Calcium Patent Litig.*, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) (excluding patent law expert's opinion directed to patentee's "supposed state of mind or intent"). Expert opinions must be "based on the 'methods and procedures of science' rather than on 'subject belief or unsupported speculation.'" *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-43 (3d Cir. 1994). Likewise, his speculation about what the examiner would have done if the facts had been different (*See* Ex. 26, Armitage Opening, at ¶¶100, 103.) is improper. *See, e.g., Ondeo*, 2003 WL 1524658, at *3; *PureWick*, 2021 WL 2593338, at *1.

IX. Motion to Exclude Testimony of Dr. Robert Perni and Dr. Robert Steed, in Part, for Improperly Opining on States of Mind and Legal Standards

Defendant Elysium Health Inc. ("Elysium") accuses several employees of Plaintiff W. R. Grace & Co.-Conn ("Grace") of inequitable conduct based upon alleged pre-critical date sales of the inventions claimed in the patents-in-suit, crystalline Form I and crystalline Form II NRCl. As discussed in Grace's 12(b)(6) motion (D.I. 136) and its concurrently filed summary judgment motion, Elysium failed even to plead its inequitable conduct claims with particularity, let alone establish a genuine dispute as to any material fact. Thus, Elysium's inequitable conduct claims should be disposed of on the pleadings or summarily. But even if those claims survive, the Court should exclude under Federal Rules of Evidence 702 and/or 403 the related testimony of Elysium's technical experts, Dr. Robert Perni and Dr. Jonathan Steed, concerning (a) Grace's and its

employees' knowledge, intent, motivations, and states of mind; and (b) the legal standards for inequitable conduct and materiality.

A. Legal Standards

It is the Court's "gatekeeping" responsibility to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. "An expert witness must have such skill, knowledge, or experience in the field as to make it appear that his opinion will probably aid the trier of fact in his search for the truth." *Aloe Coal Co. v. Clark Equip. Co.*, 816 F.2d 110, 114 (3d Cir. 1987). Expert testimony that is not based on expertise setting the expert apart from a lay juror does not satisfy the requirements of Rule 702. *Victaulic*, 2022 WL 17250376, at *7-8; *Aloe Coal Co.*, 816 F.2d at 114 ("At a minimum, a proffered expert witness . . . must possess skill or knowledge greater than the average layman . . . .").

B. Drs. Perni and Steed Should Be Precluded from Testifying As to Grace's and Its Employees' Knowledge, Intent, Motivations, and State of Mind

Drs. Perni and Steed hold themselves out as experts in chemistry. (Ex. 3, Opening Expert Report of Robert B. Perni, Ph.D. ("Perni Opening") at ¶7; Ex. 4, Opening Expert Report of Jonathan W. Steed, Ph.D ("Steed Opening") at ¶14.) Yet they repeatedly offer opinions concerning Grace's and its employees' knowledge, intent, motivations, and state of mind, which have no connection to this purported expertise. For example, Drs. Perni and Steed allege that Grace employees "***had the intent*** not to disclose [allegedly] invalidating information to the US PTO." (Ex. 3, Perni Opening ¶225; Ex. 4, Steed Opening ¶207)(emphasis added). [redacted] They also state that "Grace employees…***were aware*** that Grace's crystalline NR-Cl was the subject of commercial offers for sale and actual sales…and ***knew of its materiality***."

[redacted] They also cite assertions of attorney-client privilege as purported evidence of intent. (*See, e.g.,* Ex. 3, Perni Opening at ¶¶250-257; Ex. 4, Steed Opening at ¶¶228-232, 234.)

Indeed, Dr. Perni's and Dr. Steed's opening expert reports contain lengthy sections on "unenforceability" replete with such musings, which read more like legal briefs than scientific expert reports. (Ex. 3, Perni Opening at ¶¶221-263; Ex. 4, Steed Opening at ¶¶203-243.) And most of their respective "unenforceability" sections are nearly word-for-word identical. (See Ex. 3, Perni Opening at ¶¶221-227, 213-218, 249-253; Ex. 4, Steed Opening at ¶¶203-210, 230-235, 227-232.) They have never spoken and did not consider each other's reports, so these sections were clearly drafted by Elysium's lawyers. (*See* Ex. 29, Perni Dep. Tr. at 17:20-18:25, 20:17-21, 26:19-28:3, Ex. 22, Steed Dep. Tr. at 25:21-27:19, 18:23-19:4.) Similar "opinions" appear scattered throughout their reports. (*See, e.g.*, Ex. 3, Perni Opening at ¶¶186-187, 190-193; Ex. 4, Steed Opening at ¶¶173-174, 177-180.)

Dr. Perni's and Dr. Steed's speculation, assumptions, and alleged inferences concerning Grace's and its employees' knowledge, intent, motives, and state of mind are improper. They are based not on scientific expertise or firsthand knowledge, but solely on the experts' *post hoc* review of documents and deposition testimony. "Expert witnesses are not 'permitted to testify ... regarding [a party's] intent, motive, or state of mind, or evidence by which such state of mind may be inferred.'" *AstraZeneca LP v. Tap Pharm. Prod., Inc.*, 444 F. Supp. 2d 278, 293 (D. Del. 2006) (quoting *Oxford Gene Tech., Ltd. v. Mergen Ltd.*, 345 F.Supp.2d 431, 443 (D. Del. 2004)). For example, in *In re Rosuvastatin Calcium Patent Litigation*, the court precluded a party asserting

inequitable conduct from offering expert opinions as "circumstantial evidence relating to [an individual's] intent." 2009 WL 4800702, at *8, *report and recommendation adopted*, No. CIV.A 07-805-JJF, 2010 WL 661599 (D. Del. Feb. 19, 2010). The court rejected the argument that the testimony was merely a "frame of reference" for "the Court's inquiry into whether there was an intent to deceive the USPTO," and excluded the testimony entirely because the expert did, in fact, "seek to testify to her conclusions as to [the individual's] intent." *Id*. Similarly, in another case involving inequitable conduct, the court precluded a chemist from testifying "as to what the inventors, or [the company], knew or intended." *AstraZeneca UK Ltd.*, 2012 WL 6043266, at *2. In fact, it is well settled that such testimony is not admissible. *See, e.g., In re Fosamax Prods. Liab. Litig.,* 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009*)* (holding that "knowledge, motivations, intent, state of mind, or purposes" are not proper subjects for expert testimony); *In re C.R. Bard, Inc*., 948 F. Supp. 2d 589, 607 (S.D.W. Va. 2013) (holding that "knowledge, motive, or intent based on corporate documents…are not properly the subject of expert testimony because these are lay matters").

At deposition, Drs. Perni and Steed conceded that they are not qualified to offer such opinions. Concerning the individuals he accused of inequitable conduct in his reports, Dr. Perni admitted, "I don't know what they knew or didn't know or thought or didn't think." (Ex. 29, Perni Dep. Tr. at 302:24-303:13.) He further said, "I'm not a mind-reader. Their intent and motivations…if there were any, could have been different among all of them….I'm not speculating on any of that." (*Id. at* 303:21-304:7.) Dr. Steed similarly conceded, "[o]bviously, I can't get inside the heads of these employees, so I don't know what their intent was." (Ex. 22, Steed Dep. Tr at 250:5-21.)

Dr. Perni's and Dr. Steed's opinions on knowledge, intent, motives, and state of mind are not based on reliable scientific methodology and have nothing to do with any purported scientific, technical, or other specialized knowledge they possess. As such, those opinions should be excluded under Rule 702. Alternatively, the opinions should be excluded under Rule 403. Drs. Perni and Steed should not be allowed to provide a narrative recitation of Elysium's version of the facts cloaked in the apparent authority of expert testimony based only on their review of deposition testimony and corporate documents. This will be unfairly prejudicial, mislead the jury, waste time, and be needlessly cumulative of other evidence. The jury will be capable of drawing inferences as to individuals' intent, what they knew, and when they knew it from the documents themselves and the testimony of percipient witnesses without the aid of supposed opinion testimony from chemists. *See, e.g., In re Fosamax*, 645 F. Supp. 2d at 192 ("[A]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence.").

Thus, the Court should preclude Drs. Perni and Steed from offering testimony about knowledge, intent, motivation, or state of mind, including but not limited to the opinions expressed in Dr. Perni's Opening Report at paragraphs 186-187, 190-193, and 221-263, and in Dr. Steed's Opening Report at paragraphs 173-174, 177-180, and 203-243.

C. Drs. Perni and Steed Should Be Precluded From Testifying As to Legal Standards and Materiality

Drs. Perni and Steed also purport to offer opinions concerning the legal standards for inequitable conduct and whether undisclosed information would have been "material to patentability." For example, they state that "[t]he duty of disclosure, however, does not arise from these declarations. I understand that this duty of disclosure is set out in 37 C.F.R. § 1.56 and applies to each and every claim under consideration by the US PTO." (Ex. 3, Perni Opening at ¶230; Ex. 4, Steed Opening at ¶213.) Each further opines that "the evidence clearly shows that *if*

the…examiner had been informed of Grace's pre-critical date sales the examiner would have had sufficient information to reject those patent claims because that information now renders those claims invalid." (Ex. 3, Perni Opening at ¶244, Appendix I; Ex. 4, Steed Opening at ¶222, Appendix G.) Other instances of such testimony abound in Dr. Perni's and Dr. Steed's expert reports. (*See, e.g.,* Ex. 3, Perni Opening at ¶¶49-50, 221-223, 228-231, 244, 250-256; Ex. 4, Steed Opening at ¶¶84-85, 203-205, 211-214, 222-224, 228-235.)

This testimony is plainly inadmissible. "[E]xpert witnesses may not testify as to the law governing a dispute or offer conclusions concerning a party's compliance with legal duties" and, in particular, "experts in patent cases may not opine on whether a party engaged in inequitable conduct, discuss whether certain information was material to a pending patent application, or otherwise provide legal conclusions on 'substantive issues of patent law.'" *Brigham & Women's Hosp. Inc.*, 2010 WL 3907490, at *2. An expert may not opine "as to how the [USPTO] would have responded had certain prior art been disclosed to it" during patent prosecution. *Ondeo Nalco Co.*, 2003 WL 1524658, at *3. Thus, the Court should preclude Drs. Perni and Steed from testifying concerning legal standards and the "materiality" element of inequitable conduct under Rules 702 and 403.

X. Motion to Exclude Testimony of Dr. Perni in its Entirety For Lack of Qualifications

The patents-in-suit concern novel crystalline forms of NRCl. Thus, it is no surprise that the parties agree that a person or ordinary skill in the art (POSA) must have experience in crystallography and in identifying and characterizing crystalline solid forms. Elysium's technical expert, Dr. Perni, addresses issues required to be analyzed from the perspective of a POSA, for example, infringement and validity issues such as whether the patents ***enable a POSA*** to make and use the claimed crystalline forms. In fact, he clearly states that his assignment was "to provide

opinions . . . from the perspective of a [POSA].” (Ex. 3, Perni Opening at ¶9.) However, Dr. Perni admitted that not only is he not an expert in the requisite field, but that he does not even possess ***ordinary*** skill in the art. As such, he is not qualified to testify from the perspective of a POSA and his opinions will be neither reliable nor helpful to the jury. The Court should exclude Dr. Perni’s opinions in their entirety.

Rule 702 imposes a “trilogy of restrictions,” namely, “qualification, reliability and fit.” *Calhoun v. Yamaha Motor Corp*., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quotations omitted). To be sure, “a broad range of knowledge, skills, and training [may] qualify an expert as such.” *Id.* (quotations omitted). However, “[t]o offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art.” *Bial-Portela & CA. S.A. v. Alkem Labs. Ltd.*, 2022 WL 4244989, at *7 (D. Del. Sept. 15, 2022) (Conolly, J.) (quoting *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022)). “Without that skill, the witness’ opinions are neither relevant nor reliable. The opinions would not be based on any specialized knowledge, training, or experience that would be helpful to the factfinder.” *Kyocera,* 22 F.4th at 1377. Thus, “it is proper to exclude” an expert’s testimony if, for example, “he does not meet his own definition of a POSA.” *Takeda Pharm. Co. Ltd. v. Norwich Pharms., Inc*., 2022 WL 17959811, at *33 (D.N.J. Dec. 27, 2022).

An expert may be “generally qualified” but lack qualifications to testify outside his area of expertise. *Calhoun*, 350 F.3d at 322. Indeed, even highly credentialed experts may be excluded if they lack experience in the ***pertinent*** art or field. *See, e.g., Proveris Sci. Corp. v. Innovasystems, Inc*., 536 F.3d 1256, 1268 (Fed. Cir. 2008) (excluding mechanical engineer’s testimony about drug delivery device development equipment because his experience was limited to satellite design);

Aloe Coal Co., 816 F.2d at 114 (precluding salesman from providing expert testimony concerning cause of tractor shovel fire); *Globe Indem. Co. v. Highland Tank & Mfg. Co*., 345 F. Supp. 1290, 1291-92 (E.D. Pa. 1972), *aff'd*', 478 F.2d 1398 (3d Cir. 1973) (precluding "generally qualified" engineer from testifying as to "safety criteria" for the "design of molasses tanks" due to lack of " prior experience or observational knowledge" with said criteria); *Diaz v. Johnson Matthey, Inc*., 893 F. Supp. 358, 372-73 (D.N.J. 1995) (excluding pulmonologist's testimony about platinum allergy because he had no experience with that particular condition).

Dr. Perni might be an experienced synthetic organic and medicinal chemist. (*See* Ex. 3, Perni Opening at ¶7, attached Exhibit 1.) But in his Opening Report, he stated that a POSA "would have had a Ph.D. in chemistry, or a similar field, with 5 or more years of experience in academia or industry focused on ***crystallography and its methods of analysis***," including the analytical method known as x-ray powder diffraction or "XRPD." (*Id.* at ¶13 (emphasis added).) Elysium's other scientific expert, Dr. Jonathan Steed, offered an identical definition. (Ex. 4, Steed Opening at ¶20.) Grace's experts agree, and it is undisputed that experience in crystallography and in characterizing crystalline forms using analytical methods is required. (*See* Ex. 31, Park Opening at ¶¶18-21; Ex. 15, Rogers Rebuttal at ¶¶25-29.) Conversely, no expert opined that a POSA would have had synthetic organic or medicinal chemistry expertise. And Dr. Steed, who Dr. Perni called an "actual crystallographer," did not rely upon or consider Dr. Perni's opinions. (*See* Ex. 29, Perni Dep Tr. at 20:6-13; Ex. 22, Steed Dep. Tr. at 26:13-27:19.)

Dr. Perni admitted that he does not have the required experience in crystallography and its methods of analysis, that he does not possess the qualifications of a POSA as he has defined

them[11], and that he cannot offer opinions from a POSA's perspective. (Ex. 29, Perni Dep. Tr. at 92:7-11, 95:3-16.) Additionally, Dr. Perni does not consider himself an expert in crystallography or the identification and characterization of crystalline forms. (*Id.* at 45:16-46:7.) He is also not an expert in XRPD or in interpreting XRPD results. (*Id. at* 161:5-11.) And he is not an expert in using other analytical methods described in the patents-in-suit, like differential scanning calorimetry and IR spectroscopy, to analyze crystalline forms. (*Id.* 50:23-51:8; 51:15-20.)

Dr. Perni's entire testimony should be excluded. Infringement and validity must be analyzed from a POSA's perspective. "Admitting testimony from a person" like Dr. Perni, who has "no skill in the pertinent art, serves only to cause mischief and confuse the factfinder." *Kyocera,* 22 F.4th at 1377 (quoting *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360 (Fed. Cir. 2008)). For example, Dr. Perni's reports contain lengthy sections alleging that the patents-in-suit are "invalid under [35 U.S.C] § 112," which are littered with pronouncements regarding how a POSA would or would not "understand" the asserted claims (Ex. 3, Perni Opening at ¶¶186-220; Ex. 30, Perni Reply at ¶¶100-128.) Dr. Perni plainly cannot opine from a POSA's perspective as to the written description, enablement, and indefiniteness requirements, or as to claim scope. In addition, whether Elysium's product meets the limitations of the asserted claims and therefore infringes is also an issue that must be analyzed from the perspective of a POSA and which Dr. Perni cannot speak to. (*See* Ex. 5, Perni Rebuttal at ¶¶23-42.) His discussions concerning and analyses of XRPD and infrared spectroscopy data should also be excluded because he admittedly lacks experience with and is not an expert in using those methods to analyze crystalline

[11] Dr. Perni testified that "the Elysium attorneys" came up with the POSA definition provided in his expert reports, perhaps explaining this discrepancy. (Ex. 29, Perni Dep. Tr. at 92:12-21.)

forms. (*See, e.g.,* Ex. 5, Perni Rebuttal at ¶¶56-59; Ex. 30, Perni Reply at ¶¶22-26 44, 50-51, 77-83.)

The bulk of Dr. Perni's validity opinions concern analyses of the identity of the NRCl crystalline form(s) supposedly contained in various NRCl batches manufactured by Grace (*i.e.*, comparing the patent claims to particular samples – which must be done from the perspective of a POSA), which Elysium alleges were on sale before the critical dates of the patents-in-suit. Based on this, Dr. Perni purports to opine that patents-in-suit "are invalid for having been on sale." (Ex. 3, Perni Opening at ¶¶51-173; Ex. 30, Perni Reply at ¶¶21-71, 92-99.) Again, because Dr. Perni lacks the experience of a POSA and is not an expert in identifying crystalline forms, he cannot offer expert testimony on this subject. Dr. Perni appears to contend that he can identify the crystalline form(s) contained in Grace's NRCl batches solely based upon the manufacturing process used to make them, but he does not cite any scientific literature or other evidence in support. (*See, e.g.*, Ex. 3, Perni Opening at ¶ 165,) In fact, Dr. Perni testified at deposition that describing a crystalline form requires describing both a process for making the form ***and*** the characteristics of the form such as XRPD data because "you could perform the process and come up with something different and wouldn't know." (Ex. 29, Perni Dep. Tr. at 184:6-185:19.)

Dr. Perni is unqualified to testify as an expert and his opinions are unreliable and unhelpful to the jury. For all the foregoing reasons, Grace requests that the Court exclude his testimony in its entirety.

XI. Motion to Exclude Testimony of Alexander Clemons in Part

Grace requests that the Court preclude the expert testimony of Elysium's damages expert, Alexander Clemons, in part. Mr. Clemons should be precluded from offering testimony regarding: (1) his 50% royalty rate reduction opinion, and (2) his opinions regarding Elysium's allegedly

available non-infringing alternatives. For the reasons explained below, the proposed testimony is flawed, unreliable, and based on insufficient facts and data, thus failing to meet the *Daubert* and FRE 702 standards.

A. Mr. Clemons' 50% Reduction of the Royalty Rate Has No Ties to This Case

Mr. Clemons reduces the royalty rate stated in [redacted] by 50% using an impermissible "rule of thumb" with no ties to the facts of this case. His adjustment is based on two articles published in 2011-2012 by Thomas Varner describing a study of 1,458 miscellaneous patent license and assignment agreements included in SEC filings. (Ex. 28, Clemons Tr. at 263:24-266:8; Ex. 27, Rebuttal Expert Report of Alexander L. Clemons ("Clemons Report") pp. 64-67.)

It is black letter law that an expert may not rely on any "rules of thumb" to aid in quantifying a reasonable royalty. *See, e.g., Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1317 (Fed. Cir. 2011). Mr. Clemons' 50% royalty reduction opinion should be excluded because it has no ties to this case. *See Numatics, Inc. v. Balluf, Inc.*, 66 F.Supp.3d 934, 951-61 (E.D. Mich. 2014) (excluding quantification based on 50% rule of thumb). Mr. Clemons testified that his 50% royalty rate reduction was also based on his "own experience reviewing many, many licenses." (Ex. 28, Clemons Tr. at 263:24-264:5.) But vague references to generalized experience, which are untestable on cross-examination, cannot salvage this improper opinion. *Digital Reg of Texas, LLC v. Adobe Sys., Inc.*, 2014 WL 4090550, at *2 (N.D. Cal. Aug. 14, 2014) (excluding royalty rate testimony based on expert's "vague, undisclosed general experience").

B. Mr. Clemons' Opinions About Theoretical Alternatives Allegedly Available to Elysium are Too Speculative

Because Elysium's alleged alternatives were never marketed, Elysium must show that it had the necessary materials, equipment, know-how, and experience to make its alleged alternatives "available" at the relevant time. *Grain Processing*, 185 F.3d at 1353; *Micro Chem.,* 318 F.3d at

1123 (Fed. Cir. 2003) (alternative not available where it would have taken four months to covert infringing units into non-infringing units).

As explained in Grace's summary judgement motion on Elysium's alleged non-infringing alternatives, Mr. Clemons' proposed testimony is simply too speculative to establish whether any of Elysium's alleged alternatives were in fact available to it. In other word, his opinions and testimony are not based on sufficient facts or data regarding Elysium's alleged know-how, materials, and experience (*see* Ex. 27, Clemons Report at pp 27-36) and should therefore be precluded. *WhereverTV, Inc. v. Comcast Cable Comm'ns, LLC*, 2022 WL 2751752, *6-7 (M.D. Fla. July 14, 2022) (striking expert testimony on "many" proposed alternatives which were addressed only vaguely in the expert's report); *Laser Dynamics, Inc. v. Quanta Comput.*, 2011 WL 197869, at *3 (E.D. Tex. Jan. 20, 2011) (excluding an expert's testimony where he failed to explain how the alternatives were "available" to *the accused infringer* at the relevant time period).

In addition, Mr. Clemons improperly considers the accused infringing forms of NRCl to be non-infringing alternatives if one or a subset of patents might eventually be determined to be invalid or not infringed. (Ex. 28, Clemons Tr., at 182:19-183:15; Ex. 27, Clemons Report, at p. 36.) But it is black letter law that an alleged alternative must actually be non-infringing to be an acceptable non-infringing alternative. *See, e.g., Pall Corp. v. Micron Septations, Inc.*, 66 F.3d 1211, 1222-23 (Fed. Cir. 1995); *GlaxoSmithKline LLC v. Glenmark Pharm. Inc.*, 2017 WL 2536468, at *2 (D. Del. June 9, 2017).

XII. Motion to Exclude Testimony of Dr. Ryan Dellinger in Part

Elysium submitted an expert report signed by Dr. Ryan Dellinger, Elysium's Vice President of Scientific Affairs. Dr. Dellinger, who has a scientific background in biology, opines on (1) what would be "reasonable" or "acceptable" alternatives to the accused product (Elysium's

Basis) and to the relevant infringing ingredient (NRCl) in Basis (Ex. 32, Dellinger Rebuttal at ¶¶45-56), including from the perspective of consumers (*see, e.g., id.* at ¶¶49 ("customers . . . would be more likely to switch"; 55 ("customers . . . would not be deterred"), (2) what Elysium "would likely" do (*id.* at ¶¶41-44), and (3) partial costs for pursuing an alternative [redacted] Dr. Dellinger should be prohibited from testifying on the foregoing topics.

Elysium argues that the availability of acceptable alternatives should limit Grace's lost profits. Such alternatives must be viewed from the perspective of consumers. "Whether and to what extent [an alternative] prevents [a patentee] from showing lost sales [] depends not only on whether and when the alternative was available, but also on whether and to what extent it was acceptable as a substitute in the relevant market. ***Consumer demand defines*** the relevant market and ***relative substitutability*** among products therein." *Grain Processing,* 185 F.3d at 1355 (emphasis added) (citations omitted).

First, what are "reasonable" or "acceptable" alternatives requires an understanding as to what would be acceptable ***to consumers***, and Dr. Dellinger has no such understanding. Dr. Dellinger admitted he has no information as to what consumers would consider acceptable, does not know whether the information upon which he relies as a biologist (e.g., clinical research and data) is important to consumers, does not know what science is relayed to consumers, and does not know how the accused product is marketed. (Ex. 33, Dellinger July 2022 Tr., at 107:16-108:2 (no information on what consumers would consider acceptable); 22:19-23 (clinical research); 76:8-12 (data); Ex. 34, Dellinger January 2023 Tr., at 36:6-25 (no knowledge of marketing); 42:2-24 (no knowledge of consumer knowledge or marketing) 102:5-6 ("I'm not here to testify what Elysium customers think")). Moreover, Dr. Dellinger conceded that he did not know whether consumers themselves would consider any of the alleged alternatives to be acceptable. (Ex. 33,

Dellinger July 2022 Tr. at 103:8-11.) Given the foregoing, permitting Dr. Dellinger to opine as to (1) what would be a "reasonable" or "acceptable" alternative would be irrelevant, unreliable, and unfairly prejudicial (as that needs to be viewed from the perspective of consumers), and (2) the perspective of consumers, would be irrelevant, unreliable, and unfairly prejudicial.

Second, Dr. Dellinger opines on what Elysium would likely do if it were pursuing an alternative [redacted] yet he repeatedly testified that he is unable to speak to what Elysium thinks, what Elysium would do, and refused to answer hypotheticals as to Elysium. *See, e.g.,* (Ex. 34, Dellinger January 2023 Tr., at 141:17-142:8 ("I'm not an expert in what Elysium may or may not do as a business decision under hypothetical, you know, situations"); 31:18-25 ("I haven't thought about what Elysium would do and I don't want to opine on hypotheticals."); 146:16-24 ("I don't want to comment on a hypothetical")). As such, Dr. Dellinger should be prohibited from testifying hypothetically about what Elysium would do.

Third, Dr. Dellinger opines on certain costs associated with pursuing an alternative [redacted] but conceded that his cost estimates were incomplete [redacted]. As such, Dr. Dellinger should not be permitted to testify as

an expert as to the cost of pursuing alleged alternatives, as his testimony would be unreliable and prejudicial.

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Of Counsel:

Christopher P. Borello
Natalie D. Lieber
James R. Tyminski
VENABLE LLP
1270 Ave. of the Americas
New York, New York 10020
Tel: (212) 218-2574
cborello@venable.com
ndlieber@venable.com
jtyminski@venable.com

VENABLE LLP

/s/ Daniel A. O'Brien
Daniel A. O'Brien (No. 4897)
1201 N. Market Street, Suite 1400
Wilmington, Delaware 19801
Tel: (302) 298-3523
daobrien@venable.com

Counsel for Plaintiff

CERTIFICATE OF SERVICE

I, Daniel A. O'Brien, hereby certify that on this 25th day of January, 2023, a copy of the foregoing document was electronically filed with the court and served via CM/ECF, on parties with counsel of record identified on the Court's docket.

/s/ Daniel A. O'Brien
Daniel A. O'Brien (No. 4897)